



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,052	11/22/2006	Kimihiro Mabuchi	19461-004US1 547267	2047
26211 7590 07/05/2011 FISH & RICHARDSON P.C. (NY) P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022				
EXAMINER				
BASS, DIKK R				
ART UNIT		PAPER NUMBER		
1777				
NOTIFICATION DATE		DELIVERY MODE		
07/05/2011		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/582,052

Applicant(s)

MABUCHI ET AL.

Examiner

DIRK BASS

Art Unit

1777

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2011.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
4a) Of the above claim(s) 8-16 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-7 and 17-19 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-944)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment filed May 20, 2011 is acknowledged. Claims 8-16 are withdrawn from consideration and claims 18-19 are newly added. Claims 1-7 and 17-19 are pending and further considered on the merits.

Response to Amendment

In light of the amendment, the examiner maintains the grounds of rejection set forth in the office action dated December 20, 2010.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. **Claims 1 and 3-6** are rejected on the ground of nonstatutory double patenting over claims 1-2 and 5-7 of U. S. Patent No. 7442302 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: both the pending application and issued US patent disclose and claim a polysulfone/polyvinylpyrrolidone hollow fiber where the content of polyvinylpyrrolidone on the outer surface of said fiber is 25-50 mass %.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. **Claim 19** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Regarding claim 19, it is unclear how the maximum absorbance value is at least 0.05, when taken in combination with the independent claim where the maximum absorbance value is not larger than 0.05.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. **Claims 1-7 and 17-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Oishi et al., WO 2003/009926. For purposes of examination, the examiner is relying on the US patent publication of WO 2003/009926, hereinafter Oishi et al., US 7087168 (Oishi).

8. Regarding claims 1-2, 5, 7, and 17, Oishi discloses a polysulfone/polyvinylpyrrolidone hollow fiber membrane (abstract) wherein polyvinylpyrrolidone is present in an amount of 30-45 mass % on the inner surface of the membrane (C6, L9-12). While Oishi does not explicitly disclose the content of PVP being on the outer surface of the membrane, it would have been obvious to a routineer in the art at the time the invention was made to have the disclosed content of PVP on the outer surface, since it has been held that mere reversal of the essential working parts of a device involves only routine skill in the art (MPEP 2144 Section VI, Part A).

9. Furthermore, Oishi discloses that the PVP content is preferable since if the PVP content is too low, the surface would be too hydrophobic and absorb too much plasma protein, and if the PVP content is too high, increased amounts of PVP would elute into the blood (C6, L19-28). Therefore, it can be envisaged that the advantages disclosed in Oishi for having 30-45 mass % of PVP on the interior surface of a hollow fiber membrane can also be relevant and provide the same function when said content of PVP is on the outer surface of the hollow fiber membrane.
10. Regarding claim 3, Oishi does not explicitly disclose the porosity of the hollow fiber, nevertheless, Oishi discloses a hollow fiber with the same preferred structure as contained in Applicant's claims/specification; therefore, it is inherent that the hollow fiber has a porosity between 8-25% (MPEP 2112).
11. Regarding claim 4, Oishi discloses that the mass ratio of PVP to polysulfone is 1 to 20 mass % (C8, L66-C9, L4).
12. Regarding claim 6, Oishi discloses that the hydrophilic polymer is crosslinked so as to be insoluble in water (Claim 8).
13. Regarding claim 18, Oishi does not explicitly disclose that the mass ratio hydrophilic polymer to the polysulfone based resin is 1 to 8 mass %. However, Oishi discloses that the ratio can be as low as 10% and as high as 27%, indicating that the mass ratio is a result effective variable which can be optimized according to the desired specifications of the membrane. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claimed mass

ratio, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art (MPEP 2144.05, Section II, Part B).

Response to Arguments

14. Applicant's arguments with respect to claims 1-7 and 17 have been considered but are not persuasive.

15. Applicant argues that it would not have been obvious to rearrange the essential working parts of the membrane disclosed in the prior art, such that the hydrophilic portion is on the outer surface of the membrane. In response, the examiner maintains that it would have been obvious to reverse the parts of the membrane for reasons disclosed in Oishi.

16. Firstly, the examiner points out that language regarding the use of the membrane such as a surface "for contacting blood" and another surface "for contacting a dialyzing fluid" are statements with regard to the intended use and are not further limiting in so far as the structure of the product is concerned. In article claims, a claimed intended use must result in a **structural difference** between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. MPEP § 2111.02. Therefore, applicant's arguments with respect to the functionality of the membrane in comparison to the prior art are moot.

17. Secondly, the examiner has shown the prior art to disclose a membrane comprising polysulfone/PVP, wherein the content of PVP on a surface of the membrane is between 25-50 mass %. The prior art further discloses several advantages of having the specified hydrophilic polymer content on a surface of the membrane, including

optimized plasma protein adsorption, and reduced PVP content eluted into the blood. Therefore, the examiner maintains that it would have been obvious to a routineer in the art to have the claimed PVP content on the inner or outer surface of a hollow fiber membrane for the advantages discussed above.

18. Furthermore, the examiner maintains that mere reversal of parts of the essential working parts of a device involves only routine skill in the art, absent a showing of criticality or unexpected results.

19. Applicant argues that since Oishi discloses a mass ratio of hydrophilic polymer to polysulfone based resin equal to or higher than 10%, Oishi teaches away from a ratio range between 1 to 8 mass %. In response, the examiner does not consider Oishi to teach away from such a range, since Oishi merely states that reducing the ratio to less than 10% decreases the viscosity of the membrane forming solution. Furthermore, Oishi discloses that the ratio can be optimized according to the specific needs of the membrane, providing support that discovering the optimum value of a result effective variable involves only routine skill in the art.

Conclusion

20. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DIRK BASS whose telephone number is (571)270-7370. The examiner can normally be reached on Mon - Fri (9am-4pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KRISHNAN S MENON/
Primary Examiner, Art Unit 1777

/DRB/
Dirk R. Bass